



BRIAN E. FROSH, MARYLAND ATTORNEY GENERAL

PRESS RELEASE

**FOR IMMEDIATE RELEASE:
March 23, 2021**

Media Contacts:
press@oag.state.md.us
410-576-7009

Attorney General Frosh Announces \$188.6 Million Multistate Settlement with Medical Device Manufacturer Boston Scientific Corporation

BALTIMORE, MD — Maryland Attorney General Brian E. Frosh today announced a multistate settlement with Boston Scientific Corporation (Boston) to resolve allegations of deceptive marketing of its surgical mesh products for women. The settlement requires Boston to pay \$188.6 million to 47 states and the District of Columbia to resolve allegations that it deceptively marketed transvaginal surgical mesh devices. Maryland's share of the settlement is \$5,620,634.

"Thousands of women suffered intractable pain, incontinence or other problems because they were unaware of the health complications of transvaginal mesh," said Attorney General Frosh. "Boston Scientific had a duty to tell them about the significant risks and did not. As a result of this settlement, Boston Scientific is required to disclose important risk information to patients and doctors."

Transvaginal surgical mesh is a synthetic, polypropylene fabric that is implanted in the pelvic floor through the vagina to treat stress urinary incontinence and pelvic organ prolapse. These are common conditions faced by many women due to a weakening of pelvic floor muscles caused by childbirth, age, or other factors.

The complaint alleges that Boston misrepresented the safety of these products by failing to disclose the full range of potential serious and irreversible complications caused by mesh, including chronic pain, voiding dysfunction, and new onset of incontinence. The settlement provides comprehensive injunctive relief.

Marketing Reforms:

Under the terms of the settlement, Boston's marketing materials must:

- Disclose significant complications, including the inherent risks of mesh;
- Describe complications in understandable terms to consumers, for those marketing materials intended for consumers that address complications;

- Refrain from representing that any inherent risks of mesh are risks common to any pelvic floor or other surgery not involving mesh;
- Refrain from representing that inherent mesh complications can be eliminated with surgical experience or technique alone;
- Refrain from representing that its mesh does not cause a foreign body reaction;
- Refrain from representing that its mesh remains soft, supple, or pliable after implantation;
- Refrain from representing that its mesh does not potentiate infection or does not increase the likelihood of infection; and,
- Refrain from representing that using its mesh for a repair is superior to native tissue repair unless such representations are supported by valid scientific evidence.

Training Reforms:

The settlement also requires Boston to:

- Inform healthcare providers of significant complications and inherent mesh risks when providing training regarding procedures for insertion and implantation of its mesh; and
- Maintain policies requiring that its independent contractors, agents, and employees who sell, market, or promote its mesh are adequately trained to report patient complaints and adverse events to the company.

Reforms Concerning Clinical Information and Clinical Trials:

Under the terms of the settlement, Boston is required to:

- Present clinical information regarding its mesh in a truthful, non-misleading manner and with a balanced presentation of risks in relation to benefits;
- Refrain from misrepresenting clinical studies about its mesh;
- When submitting a clinical study or clinical data regarding its mesh for publication, disclose the company's role as a sponsor and any author's potential conflict of interest;
- Include a sponsorship disclosure provision requiring consultants on surgical mesh to contractually agree to disclose in any public presentation or submission for publication any sponsorship by Boston related to the contracted-for activity; and
- Register all Boston-sponsored clinical studies regarding its mesh with ClinicalTrials.gov.

Attorney General Frosh's office helped to lead the investigation and settlement negotiation.

<https://www.marylandattorneygeneral.gov/press/2021/032321.pdf>